

REMARKS

By this amendment, applicants have amended claim 10 to recite that the apparatus includes a filter by which a stool suspension produced in the bag can be filtered to remove an impurity in the sample and to recover filtered solution (see, e.g., page 10, line 6 to page 11, line 6 of applicants' specification), that the solid carrier has a surface having an affinity for cancer cells (see, page 11, lines 9-15 of applicants' specification) and that the apparatus includes a dispensing portion for dispensing the filtered solution directly into the container (see, Fig. 4 and page 13, lines 14-20 of applicants' specification). Claim 11 has been canceled without prejudice or disclaimer. Claim 12 has been amended to depend from claim 10, and claims 12-14 amended to change "said" to read "the."

Applicants have also added claims 16-21 to define further aspects of the invention. Claim 16 is supported by the description at page 10, lines 12-15 of applicants' specification. In this regard, clearly the word "size" refers to the pore size and not other dimensions of the filter; this is confirmed by the description at page 10, lines 23-26 of applicants' specification, which indicates the other dimensions of the filter (e.g., diameter and height) are on the order of millimeters. Claims 17-19 are supported by the description at page 10, lines 8-11 of applicants' specification. Claim 20 is supported by the description at page 11, lines 9-12 of applicants' specification. Claim 21 is supported by Fig. 4 and page 13, lines 14-24 and page 19, lines 10-21 of applicants' specification.

In view of the cancellation of claim 11 and the amendments to claim 12, including the change in dependency thereof, it is submitted the rejection of claims 11 and 12 under 35 U.S.C. §112, second paragraph, is moot.

Claims 10-15 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0059839 A1 to Obiso et al. Applicants traverse this rejection and request reconsideration thereof.

The rejected claims relate to a cell recovery apparatus for recovering cells from stool. The apparatus is useful for recovering cells useful for the detection of colorectal cancer. The apparatus includes a bag for storing a sample comprising a buffer solution and stool at room temperature, a filter by which a stool suspension produced in the bag can be filtered to remove an impurity in the sample and to recover filtered solution, a solid carrier having a surface having an affinity for cancer cells, and a container in which the solid carrier and the filtered solution can be stored. In accordance with the method and apparatus of the invention for cell recovery, good, living cancer cells can be recovered from stool at room temperature, in contrast to the cooling method as disclosed in JP Patent Publication (Kohyo) No. 11-511982 A (1999) (WO97/09600), whereby the surface of a cooled and frozen stool is scraped and then cancer cells existing in the surface of the stool are exfoliated. Thus, in accordance with the invention, the recovered cells can be subjected to cytological, immunological and biochemical analyses with high accuracy. Also, since the apparatus of the invention can utilize a cell deriving from early colorectal cancer or the stool as a whole as a specimen, cancer cells deriving from the ascending colon, which are difficult to detect endoscopically, can be recovered. Thus, the invention can provide a highly reliable examination method. Further, the apparatus of the invention can eliminate centrifugation and cooling operations so that the operation can be simplified and performed in less time. Thus, an automated total system for colorectal cancer examination can be constructed using the apparatus of the invention. See, page 7, lines 11-26 of applicants' specification.

The Obiso et al publication discloses a method for the detection, either qualitatively or quantitatively, of gastrointestinal microorganisms in samples, preferably fecal samples, using immunoassays, preferably electrochemiluminescence (ECL) immunoassays. The methods involve detection without the conventional processing steps typically required for such detection (e.g., lysing, enrichment, separation, or purification). The method comprises dilution of the sample thought to contain a specific microorganism, inactivation (e.g., heat inactivation) of the diluted sample, removal of solids from the inactivated diluted sample, and detection of the pathogen in the inactivated diluted sample, by conducting an electrochemiluminescence assay for a bound complex of antibody and antigenic derivative, thereby detecting and/or presumptively identifying the microorganism in the sample.

The Examiner alleges the "bag" of the present invention to read on the containers disclosed in Obiso et al. Whether or not this is the case (which is not admitted by applicant), clearly Obiso et al do not disclose a solid carrier having a surface having an affinity for cancer cells. Accordingly, the Obiso et al publication does not anticipate the presently claimed invention.

Claims 10 and 13-15 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,891,651 to Roche et al. This rejection appears to be repeated in sections 8 and 9 of the office action. Applicants traverse this/these rejection(s) and request reconsideration thereof.

The Roche et al patent discloses a method of recovering colorectal epithelial cells or fragments thereof from a stool sample. The method involves contacting a stool sample with a specific binding reagent having specificity for colorectal epithelial cells or membrane fragments thereof to form a complex containing the specific binding reagent and the colorectal epithelial cells or fragments thereof, and

separating the complex from the sample. A method of detecting dysplastic colorectal epithelial cells or fragments thereof is also disclosed, in which a specific binding reagent employed in the method has specificity for dysplastic colorectal epithelial cells or membrane fragments thereof. An article of manufacture containing reagents for performing the method is further disclosed.

As apparently recognized by the Examiner (see the paragraph bridging pages 7 and 8 of the office action), the Roche et al patent does not disclose a filter by which a stool suspension produced in the bag can be filtered to remove an impurity in the sample and to recover filtered solution. Nor does the Roche et al patent disclose a dispensing portion for dispensing the filtered solution directly into the container for storing filtered solution and solid carrier. Rather, in Roche et al, it is disclosed that, in the laboratory, a dispersing medium typically is added, and the sample is further dispersed in a laboratory blender such as a stomacher; the sample may then be tested or the sample may also be centrifuged, the supernatant discarded, and the pellet resuspended, resulting in a sample ready for testing. The use of a filter and a dispensing portion for dispensing the filtered solution directly into the container for storing filtered solution and solid carrier eliminates the need for a centrifuge and enables the recovery of cancer cells from whole stool including the central portion thereof without using a centrifuge (see, especially claim 21), whereby a small amount of cancer cells can be recovered surely and simply. Such is neither disclosed nor suggested by Roche et al. Accordingly, the Roche et al patent does not anticipate the presently claimed invention.

Claims 10 and 13-15 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,534,280 to Nair. Applicants traverse this rejection and request reconsideration thereof.

Nair discloses a method for isolating viable, biologically substantially pure exfoliated fecal colonocytes at normal ambient temperature. Immunocoprocytes and inflammatory cells indicative of certain gastrointestinal conditions and a noninvasive method for detecting colorectal cancer are set forth. Compositions of transport and suspension media for isolation of colonocytes are detailed.

It is submitted the Nair patent does not disclose the combination of a bag for storing a sample comprising a buffer solution and stool at room temperature, a filter by which a stool suspension produced in the bag can be filtered to remove an impurity in the sample and to recover filtered solution, a solid carrier having a surface having an affinity for cancer cells, a container in which the solid carrier and the filtered solution can be stored and a dispensing portion for dispensing the filtered solution directly into the container. Rather, the Nair patent (see, e.g., Fig. 1 and the description thereof) discloses that the stool sample 10 is thoroughly dispersed in medium 12, for example by vortexing, after which the contents of tube 11 are filtered through a mesh screen into a new tube 13 and underlaid with a heavy medium 14 having a density in the range of about 1.033 to about 1.25 and centrifuged in a table top centrifuge with the brakes off. Thus the Nair patent does not disclose and a dispensing portion for dispensing the filtered solution directly into the container for storing filtered solution and solid carrier. The use of a dispensing portion for dispensing the filtered solution directly into the container for storing filtered solution and solid carrier eliminates the need for a centrifuge and enables the recovery of cancer cells from whole stool including the central portion thereof without using a centrifuge (see, especially claim 21), whereby a small amount of cancer cells can be recovered surely and simply. Such is neither disclosed nor suggested by Nair. Accordingly, the Nair patent does not anticipate the presently claimed invention.

Claims 10-15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Roche et al (see section 12 of the office action) or Nair (see section 13 of the office action) in view of U.S. Patent No. 6,176,836 to Trudil et al. Applicants traverse this rejection and request reconsideration thereof.

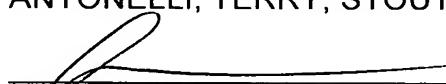
The deficiencies of Roche et al and Nair et al are noted above. The patent to Trudil et al has been cited by the Examiner as disclosing a biological sample collection kit including a collection bag having a filter attached thereto. However, it is submitted the Trudil et al patent does not remedy any the basic deficiencies of Roche et al and Nair noted above. Therefore, the presently claimed invention is patentable over the proposed combination of references.

In view of the foregoing amendments and remarks, favorable reconsideration and allowance of the application are requested.

To the extent necessary, applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to the deposit account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (Case: 1021.43503X00), and please credit any excess fees to such deposit account.

Respectfully submitted,

ANTONELLI, TERRY, STOUT & KRAUS, LLP



Alan E. Schiavelli
Registration No. 32,087

AES/at
(703) 312-6600